IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter J. Sims

Serial No.: 09/020,393 Group Art Unit: 1654

Filed: February 9, 1998 Examiner: B. Celsa

For: ***COMPOSITIONS AND METHODS TO INHIBIT FORMATION OF THE C5B-9 COMPLEX OF COMPLEMENT***

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT AND ELECTION OF SPECIES

Sir:

The following remarks are in response to the Office Action mailed February 4, 1999.

The Examiner has divided the claims into thirty-two groups:

- Group I Claims 1-3 and 7, drawn to an antibody protein to CD59 (42-58)
- Group II Claims 10-12, 16, and 17, drawn to the use of an antibody protein to CD59 (42-58) and composition thereof for inhibition formation of human C5b-9 complex
- Group III Claims 20-22 and 26, drawn to an antibody protein to C9 (359-384
- Group IV Claims 27-29 and 33, drawn to use of an antibody protein to C9 (359-384)

to promote formation of human C5b-9 complex

- Group V — ~~Claims 1-3, 7, 20-22, and 26, drawn to an anti-idiotype antibody to both~~ CD59 (42-58) and C9 (359-384) and composition thereof
- Group VI — Claims 10-12, 16, 17, 27-29, and 33-35, drawn to the use of an anti-idiotype antibody to both CD59 (42-58) and C9 (359-384) and composition thereof for inhibiting and/or promoting formation of human C5b-9 complex
- Group VII — Claims 1, 2, 4, and 26, drawn to a chimeric protein comprising CD59 (42-58) and composition thereof
- Group VIII — Claims 10, 11, 13, 16, and 17, drawn to the use of a chimeric protein comprising CD59 (42-58) and composition thereof to inhibit human C5b-9 complex
- Group IX — Claims 20, 21, and 26, drawn to a chimeric protein comprising human C9 (359-384)
- Group X — Claims 27, 28, 30, and 33-35, drawn to the use of a chimeric protein comprising human C9 (359-384) to promote formation of human C5b-9 complex
- Group XI — Claims 1, 2, 6, 7, and 26, drawn to a linear peptide comprising human CD59 (42-58) and composition thereof
- Group XII — Claims 10, 11, and 15-17, drawn to the use of a linear peptide comprising

human CD59 (42-58) and composition thereof to inhibit human C5b-9 complex

- Group XIII — Claims 20, 21, 25, and 26, drawn to a linear peptide comprising human C9 (359-384) and composition thereof
- Group XIV — Claims 27, 28, and 32-35, drawn to the use of a linear peptide comprising human C9 (359-384) and composition thereof to promote formation of human C5b-9 complex
- Group XV — Claims 1, 2, 5-7, and 26, drawn to a cyclic peptide comprising human CD59 (42-58) and composition thereof
- Group XVI — Claims 10, 11, and 14-17, drawn to the use of a cyclic peptide comprising human CD59 (42-58) and composition thereof to inhibit human C5b-9 complex
- Group XVII — Claims 20, 21, and 24-26, drawn to a cyclic peptide comprising human C9 (359-384) and composition thereof
- Group XVIII — Claims 27, 28, and 31-35, drawn to the use of a cyclic peptide comprising human C9 (359-384) and composition thereof to promote formation of human C5b-9 complex
- Group XIX — Claims 7-9 drawn to a peptidomimetic comprising the sidechains of human CD59 (His,Asn,Asp,Thr,Thr,Arg,Glu 44,48,49,51,52,55 and 58,

respectively) and composition thereof

- Group XX Claims 10, 11, and 16-19, drawn to the use of a peptidomimetic compound comprising the sidechains of human CD59 (his,Asn,Asp,Thr,Thr,Arg,Glu 44,48,49,51,52,55 and 58, respectively) and composition thereof to inhibit the formation of human C5b-9 complex
- Group XXI Claims 1,2, and 7, drawn to a DNA nucleic acid and composition thereof
- Group XXII Claims 10, 11, 16, and 17, drawn to use of a DNA nucleic acid and composition thereof to inhibit C5b-9 complex
- Group XXIII Claims 1, 2, and 7, drawn to an RNA nucleic and composition thereof
- Group XXIV Claims 10,11, 16, and 17, drawn to the use of an RNA nucleic acid and composition thereof to inhibit formation of human C5b-9
- Group XXV Claims 20, 21, and 26, drawn to a DNA nucleic and composition thereof
- Group XXVI Claims 27, 28, and 33-35, drawn to a DNA nucleic acid and composition thereof to promote formation of the human C5b-9 complex
- Group XXVII Claims 20, 21, and 26, drawn to an RNA nucleic acid and composition thereof
- Group XXVIII Claims 27, 28, and 33-35 drawn to the use of an RNA nucleic acid and composition thereof to promote formation of human C5b-9 complex
- Group XXIX Claims 1, 2, and 7, drawn to "small molecules" which bind "specifically" to human C9 (359-384) and composition thereof, which are only

classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule"

- Group XXX Claims 10, 11, 16, and 17, drawn to the use of "small molecules" which bind "specifically" to human C9 (359-384) and compositions thereof to inhibit human C5b-9 complex, classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule"
- Group XXXI Claims 20, 21, and 26, drawn to "small molecules" which bind "specifically" to human CD59 (42-58) and compositions thereof, which are only classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule"
- Group XXXII Claims 27, 28, and 33-35, drawn to the use of "small molecules" which bind "specifically" to human CD59 (42-58) and compositions thereof to promote the formation of human C5b-9 complex, which is only classifiable upon selection of an ultimate compound species due to the indefiniteness of the term "small molecule"

and additionally classified them by species: a) peptides, b) proteins, c) antibodies, d) nucleotides, and e) "small molecules".

The restriction requirement and election of species are improper and are therefore traversed. The question of separate inventions (i.e., requiring restriction) and election of species

(i.e., requiring election) have been confused. The legal basis for this is discussed in more detail below. Based on a review of the claims and the office action, a reasonable grouping of claims for a restriction requirement, and the grouping elected for prosecution by applicants, is the method of use claims to decrease inhibition of formation of the C5b9 complex, using a molecule that is designed and/or selected based on the unifying discovery that it is a very small region of CD59 that is critical to inhibition of the formation of the complex by CD59. This region is defined by amino acid residues 42-58 of human CD59. These method claims are claims 10-19 (which were separated into groups II, VI, VIII, XII, and XVI). Molecules which are made using techniques known to those skilled in the art, but which are selected for based on this discovery, include the following which were designated as species by the examiner: antibodies to amino acids 42-58 of CD59 (claims 10-12, 16, 17, group II, claims 10-12, 16, 17, group VI), chimeric proteins (claims 10, 11, 13, 16, 17, group VIII), linear peptides (claims 10, 11, 15-17, group XII), cyclic peptides (claims 10, 11, 14-17, group XVI), and peptidomimetics (claims 10, 11, 16-19, group XX).

Assuming these are the species, applicant elects the species of the antibodies defined by claism 10-12, 16, and 17, group II.

Restriction requirements and elections of species requirements are based on 35 U.S.C. § 121 allowing applicant to claim a single invention. If two or more independent or *patentably distinct* inventions or species are claimed, restriction between them is proper. It is axiomatic that inventions or species are patentably distinct *only if they are not obvious over each other*. In this

case, this would mean that one skilled in the art would not find it obvious to decrease inhibition of the assembly of the C5b9 complex using a linear peptide composed of amino acids 42-58 of CD59 from a showing that an antibody binding of amino acids 42-58 of human CD59 decreases inhibition of the C5b9 complex. Should the examiner maintain such a position, an obviousness-type double patenting rejection cannot later be made between these claims.

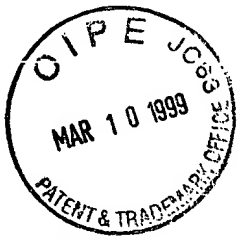
The examiner has acknowledged that the independent claim is generic. If a generic claim is allowable over the prior art, there can be no concern about the distinctness of various species encompassed by the generic claim (see 37 C.F.R. § 1.141). Even if the species were patentably distinct (i.e., separate inventions), an allowable generic claim renders moot the effort to limit the application to a single invention defined by each species. Applicant asserts that, in the present case, since claim 10 is clearly generic to the species asserted by the Examinerin the Office Action, the presence of species encompassed by claim 10 in this application is entirely proper and should not be subjected to a further restriction requirement.

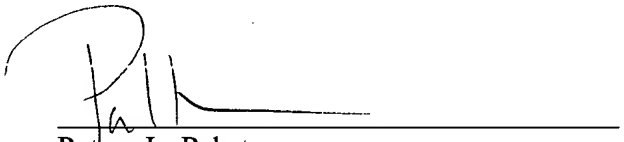
The Examiner is well aware of the changes in U.S. patent law that limit term of an issued patent to twenty years from the priority date, and the substantial costs incurred in simultaneous prosecution of multiple applications (**32 in this case!**), which in particular places an undue burden on small entities such as non-profit research institutions (such as the assignees of this application). In the present case, it is believed that while there are indeed separate inventions, there are not thirty-two separate inventions.

Reconsideration and an action on the merits of claims 10-19 is earnestly solicited.

Should the Examiner maintain the thirty-two restriction requirement, applicant hereby petitions for review of this Restriction Requirement. It is believed no fee is due. However, should a fee be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account No. 01-2507. Applicants enclose a duplicate of this document to facilitate this process.

Respectfully submitted,





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Date: March 4, 1999

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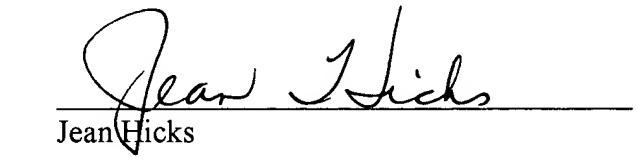
I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.



Jean Hicks

Date: March 4, 1999